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Certificate of Analysis

December 9, 2025

Viral Safety Reference Material	
Indication	Viral Safety Reference Materials (VSRM) are intended for use in viral safety assay development, method suitability, matrix spike studies, and adventitious agent detection workflows. The materials are designed to support approaches consistent with current WHO expectations for adventitious virus detection and reference material use, as well as viral safety principles described in ICH Q5A(R2). VSRM provide well-characterized viral materials for spiking product-specific matrices to assess analytical sensitivity, recovery, matrix effects, and overall method performance during development, suitability, and investigation activities. For additional use-case information, please refer to page 2 of this document.
Virus Description	
Material	Purified PCV-1
Catalog Number	SD-XXXXX
Agent	Porcine Circovirus Type 1 (PCV-1)
Biosafety Level	2
Storage Temperature	-70ºC or below
Production Method	Virus propagated in PK-15 cells in EMEM with Fetal Bobine serum and antibiotic. Supernatant and cell extract collected, sonicated, and clarified by centrifugation.
Purification Method	Clarified viral material was purified by PEG precipitation, treated with turbonuclease, then purified by ultracentrifugation through a cesium chloride gradient. Purified viral band was then dialyzed into stabilization buffer.
Final formulation	10mM Tris-HCl,135mM NaCl, 5mM MgCl2, 5% sucrose.
Inactivation	None
Lot Number	X####X
Volume per vial	500 µL
Infectious titer by PCR-based $TCID_{50}$	5.6 x 10^7 infectious units per mL
Genomic concentration determined via ddPCR quantitation	9.2 x 10^{11} copies per mL
Host Cell Background via ddPCR quantitation	6.1 x 10^3 copies per mL
Fungal & Bacterial contamination testing Microbiologics SOP QCP005	Pass No Growth
Mycoplasma Test Result	Negative
Bacterial Endotoxin LAL Test Result	<0.005 EU/mL
NGS Sequencing	Full virus genome coverage
Reference NCBI Accession Number	NC_001792.2

Material is highly infectious and must be handled under Biosafety Level 2 containment. Repeated freeze thaws are not recommended. For laboratory reference and research use only. Not for human or diagnostic use.

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Use in method development and suitability assessment
Viral Safety Reference Materials (VSRM) support product- and matrix-specific method development, method suitability, and assay performance assessment for workflows relevant to viral safety and adventitious agent detection.
The specific study design, including matrix selection, spike strategy, number of test conditions, and viruses evaluated, must be defined by the user based on the intended application, applicable regulatory expectations, and internal quality requirements.
Matrices used for evaluation should represent the final product or the relevant manufacturing stage, as defined in the study plan.
This document does not define a complete validation or qualification protocol. Such studies should be designed and executed by the user in accordance with applicable internal procedures and relevant regulatory guidance, including current WHO concepts for adventitious virus detection and reference materials, as well as the viral safety principles described in ICH Q5A(R2). For additional information on use cases, refer to page 2.

Matrix suitability and spike studies
Matrix suitability and spike studies are used to demonstrate that the user's product-specific matrix supports detection of the spiked viral material and does not adversely affect sample processing, nucleic acid recovery, or analytical detection.
For this purpose, VSRM may be spiked into the matrix and processed through the user's complete workflow. Successful detection supports assessment of recovery, matrix effects, analytical sensitivity, and overall method performance within the intended application.
If reduced recovery, interference, or other matrix effects are observed, the sample preparation procedure, matrix handling approach, or study design should be adjusted before further method development, suitability assessment, or investigational use.

Precautions
- VSRM are intended for research use, assay development, method suitability, and related investigational applications by trained laboratory personnel using good laboratory practices.
- Customers are responsible for determining suitability for their intended application and for establishing internal use periods based on their specific storage, handling, and use conditions. It is recommended to requalify material 24 months after receipt.
- Users should handle all materials, test articles, and spiked matrices in accordance with their institutional biosafety procedures and applicable laboratory requirements.
- Appropriate personal protective equipment should be worn at all times, including lab coat, gloves, and other protective equipment as required by the user's laboratory procedures.
- To minimize contamination or cross-contamination, use dedicated equipment and appropriate contamination control practices throughout sample preparation and analytical testing.
- Avoid repeated freeze-thaw cycles and do not use the material outside its recommended storage conditions.
- VSRM are intended to support method development, suitability assessment, and related use cases only. They are not intended to establish a complete validation protocol or to replace the user's internal study design, qualification strategy, or regulatory responsibilities.
- User results for quantification may vary based on the individual facilities exact test methods and protocols used.
- Dispose of unused materials and consumables in accordance with local institutional and laboratory waste procedures.

Reviewed,
Shannon Orias
Director of Virology Operations